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EXAMINER

OCAMPO, MARIANNE S

ART UNIT	PAPER NUMBER
1723	14

DATE MAILED: 09/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/518,342	HUSEK, PETR
Examiner	Art Unit	
Marianne S. Ocampo	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extension of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 June 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-14 and 33-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-14 and 33-55 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 30 October 2000 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 1 – 14 and 33 – 55 are pending. After reviewing the amendments filed on 6-24-02, the examiner noticed a misnumbering of the claims. There was no claim 49. In page 4 of the amendments (Paper no. 13) filed on 6-24-02, claim 50 comes right after claim 48. Applicants are hereby advised that the total number of claims currently pending is only 37 and not 38. According to 37 CFR 1.126, **claims 50 – 56 filed with the amendments (Paper no. 13) on 6-24-02, have been renumbered as claims 49 – 55.**

Previously Indicated Allowable Subject Matter

2. All previously indicated allowable subject matter, in the last office action (Paper no. 11) are hereby withdrawn in view of the newly found references or prior art, Mehl (US 4,774,058), Updike (US 4,138,474) and Bozzacco et al. (US 2,806,509).

Foreign Priority

3. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Czech Republic on 3-4-99. It is noted, however, that applicant has not filed a certified copy of the PV 769-99 application as required by 35 U.S.C. 119(b).

Specification

4. The disclosure is objected to because of the following informalities:
- a). the word "ha" after the word "but" and before the word "broader", should be changed to "has" in page 2, line 16.
 - b). the word "flitter" before the number "14", should be changed to "filter" in page 7, line 4.
 - c). the number "24" after the word "setter", should be changed to "26" in page 7, line 31.
 - d). the number "19" after the word "ends", should be changed to "18" in page 9, line 17.
 - e). the word "pipette" should be inserted before the word "tip" in page 12, lines 7 and 14 & page 13, lines 7, 11 & 21 in order to distinguish it from the distal tip or end (18).
 - f). the word "distal" should be inserted before the word "tip" in page 12, lines 8, 16, 18 – 19, 21, 23, 25 & 27 – 28 and page 13, line 14, in order to distinguish it from the pipette tip (12).
 - g). The same name should be used for the same structure or element, in order to avoid confusion, therefore, one of the following names for the structural element, designated as 18, i.e. the distal end or distal tip, should be used. See examples in pages 9 – 10 of the specification.

Appropriate correction is required.

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the claimed limitation of claims 11 and 45, “the opening having a diameter **about 2 –10 times** the maximum diameter of the sorbent material” lacks proper antecedent basis in the specification. There is however, support for, in the specification for an opening size of about 3 to 10 times (i.e. about 3 – 10 times) the size of the sorbent material, and at least 2 times the largest media used in the sorbent material, as in page 10.

Drawings

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character “16” has been used to designate both the sorbent volume, as in page 13, line 6 and a porous layer, as in page 13, lines 10 & 12.

7. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character “19” has been used to designate both the opening at the distal tip/end of the pipette tip, as in page 12 and the one of the ends of the sorbent cartridge 27, as in page 9, lines 16 - 17.

8. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the claimed feature, “the sorbent comprising a plurality of particles filling between about 50-60% of the sorbent volume”, in claim 43, must be shown or the feature must be canceled from the claim. **No new matter should be entered.** *Only Fig. 2 shows the sorbent material in the sorbent volume 16, and the sorbent material fills all of the sorbent volume (16).*

9. Similarly, the drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the claimed feature, “the sorbent material **substantially filling** the sorbent volume”, in claim 38, must be shown or the feature must be canceled from the claim. **No new matter should be entered.** *In fig. 2, in which the sorbent material in the sorbent volume 16 is shown, the sorbent material fills all the sorbent volume.*

10. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

11. Claims 1, 33, 47 and 50 (filed as claim 51) are objected to because of the following informalities:

- a). the article/word “an” should be placed or inserted before the word “opening” in line 4 of claim 1. It is unclear if the word “opening” is a noun or a verb (in -ing form). The examiner considered the term “opening” to be a noun.
- b). the phrase “the opening the hollow tip” in claim 33, line 5, is incomplete and grammatically incorrect, and therefore, the word “in” should be inserted before the phrase “the hollow tip” and after “the opening” in order to correct this problem.
- c). the word “dip” in claim 47, line 2 should be changed to “tip”.
- d). the phrase “the opening in tip” in line 2 of claim 51 is grammatically incorrect, and should be rewritten as “ the opening in the pipette tip”.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 43 - 44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

a). With regards to claim 43, there is no support for the claimed limitation, "**the sorbent comprises a plurality of particles filling between about 50 – 60% of the sorbent volume**", from the original disclosure or the original figures/drawings filed with the original specification. This is considered new matter and therefore, must be canceled. The statement in page 9, lines 9 – 10, does not provide sufficient evidence that the inventor, at the time the application was filed, had possession of the claimed invention. What the statement in page 9, lines 9 – 10 provides is that the sorbent volume can only hold/contain about 50 – 60% (solid) sorbent material.

b). Concerning claim 44, there is no support for the claimed limitation of the cartridge further comprising **a frit or screen at the opening**, as claimed. This is considered new matter and therefore, must be canceled. There is however support for a porous layer (also indicated as 16) on an interior end of the sorbent volume (16), which may be above but not at the opening (19), as in page 13, lines 10 – 13.

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 2, 4, 8 – 14, 33, 38, 43 and 45 - 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a). Claim 2 recites the limitation “the pipette” in line 2. This is the first time that a pipette, which is not the same as a pipette tip, is being claimed, and therefore, this limitation lacks proper antecedent basis in the claim.

b). Claim 4 recites the limitation “the size of the opening being **about 2 –10 times** the size of the material in the sorbent material”. What range of values are being included in this highlighted range? In other words, the term “about” in the claim deemed the claim to be indefinite because it is unclear what “about 2 – 10 times” mean. Does it mean about 2 or about any number between 2 and 10? What range of numbers/values is considered about 2 times or even about 2 – 10 times? Furthermore, the specification provides support for an opening size of about 3 to 10 times (i.e. about 3 – 10 times) the size of the sorbent material, and at least 2 times the largest media used in the sorbent material. There is no mention of any values or examples defining the claimed range “about 2 – 10 times” mean in the specification.

c). Claim 8 recites the limitation “the barrier” in line 5. There is insufficient antecedent basis for the limitation in the claim. Is the barrier the same structural element already claimed or mentioned as “filter” in line 4, or not? For examination purposes, the examiner considered that the barrier is indeed the same structure also named as “filter”.

d). Claims 11 and 45 both recite the limitation “the distal opening having a diameter of **about 2 –10 times** the maximum diameter of the sorbent material”. What range of values are

being included in this highlighted range? In other words, the term “about” in the claim deemed the claim to be indefinite because it is unclear what “about 2 – 10 times” mean. Does it mean about 2 or about any number between 2 and 10? What range of numbers/values is considered about 2 times or even about 2 – 10 times? Furthermore, the specification provides support for an opening size of about 3 to 10 times (i.e. about 3 – 10 times) the size of the sorbent material, and at least 2 times the largest media used in the sorbent material. There is no mention of any values or examples defining the claimed range “about 2 – 10 times” mean in the specification. Is the applicant claiming the diameter or size of the opening?

e). Claim 12 recites the limitation “the syringe” in line 1. There is insufficient antecedent basis for this limitation in the claim. It is unclear if claim 12 is adding a further limitation of a syringe, thus making the claimed invention a combination of a pipette tip/sorbent cartridge with a syringe connected thereto, or not. Claim 9 from which claim 12 depends from, has been considered to merely adding the second opening and only capable of use with a syringe and not necessarily adding the syringe to the claimed invention.

f). Claims 9 - 10 and 13 - 14 are dependent claims of claim 8, and therefore, they also suffer the same defects since they depend therefrom.

f). Claim 33 recites the means plus function language “means for retaining a porous barrier at a predetermined location” in line 4, thereby invoking the 6th paragraph of this code (35 USC 112). Applicant is hereby being given notice that the only structural means or element that could perform the specific function to satisfy the *means plus language* in claim 33, is that of the tapering of the walls of the pipette tip (as in fig. 3) or the tapered configuration of the sidewall of

the filter (as in fig. 2) in order to frictionally engage the walls of the cavity in the pipette tip, according to pages 6 – 7 and 12 - 13 of the original specification.

g). Claims 38 and 48 both recite the limitation “the sorbent material substantially fills the sorbent volume”. The term “substantially” in this claim make the claim indefinite since it is not define clearly or no numerical ranges are given in the specification to define what “substantially fills” mean. There is no mention of a specific amount or range of values as to what “substantially fills” mean in the specification (see page 10). The statement “the sorbent volume (16) once filled will hold about 50 – 60% solid sorbent”, in page 10 lines 9 – 10, does not mean the sorbent material occupies about 50 – 60% of the sorbent volume.

h). Claim 46 recites the limitation “allowing the passage of liquids” in the last line of the claim. There is insufficient antecedent basis for the limitation in the claim. It is unclear if claim 46 is narrowing the limitation of “processing fluids” which are being passed through the barrier to that only of “liquids”, or not.

i). Claim 47 is dependent claims of claim 46, and therefore, it also suffers the same defects since it depends therefrom.

j). Renumbered claims 49 and 50 (filed as claims 50 and 51) recite the limitation “the distal tip” in line 1. There is insufficient antecedent basis for the limitation in the claims.

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 1, 4, 8 – 9, 11, 35, 37 – 38 and 43 - 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Mehl (US 4,774,058).

18. Concerning claim 1, Mehl discloses a sorbent cartridge (10, 30, 40) for use in preparation of samples for chemical analysis comprising a pipette tip (12, 32) having a longitudinal axis and a hollow distal tip (16) with tapered walls defining an interior cavity extending along the axis and an opening at a distal end of the tip, a (first, at the top) porous barrier (in the form of top membrane or retainer 38, 44) in the tapered cavity placed at a predetermined location in the pipette tip (12, 32) to define a sorbent volume between the barrier (38, 44), the cavity walls of the pipette tip (12, 32) and the opening (being covered by another porous barrier 18, 36, 44) at the distal end of the pipette tip (12, 32), wherein the (first) barrier (38, top membrane 44) allowing processing fluids to pass through the barrier (38, 44), and further comprising a sorbent material (34, 42) in the sorbent volume and extending from the opening (at the vicinity of the lower porous barriers/filters 36, 44) toward the barrier (top filters or membranes 38, 44) and the sorbent material (34, 42) being selected for use in chemical analysis (i.e. absorption, filtration or separation of a particular constituent of a fluid) and the

barrier (38, 44) being selected to prevent passage of the sorbent material (34, 42) out of the sorbent volume, as in figs. 2, 5 and 7 and cols. 3 – 5.

19. With respect to claim 4, Mehl also discloses the size of the opening in the pipette tip (near the distal/bottom end of pipette tip 40) is from about 2 – 10 times the size of the material used in /as the sorbent material (42), as in fig. 7.

20. Regarding claim 8, Mehl further discloses a sorbent cartridge (10, 30, 40) comprising a pipette tip (12, 32, 40) having an interior cavity in fluid communication with a distal opening (at the bottom end thereof) located in the tip, a filter (38, 44) placed in the pipette tip (30, 40) and defining a predetermined volume that extends between the filter/barrier (38 or top membrane, 44) and the distal opening (being covered by another filter/barrier 36 or bottom membrane 44) and a sorbent material (34, 42) substantially filling the volume and the filter (38 or 44) retaining the sorbent material (34 or 42) in the predetermined volume while allowing the passage of processing fluids through the filter during use of the cartridge (30 or 40), as in figs. 5 & 7 and in cols. 3 – 5.

21. Concerning claim 9, Mehl further discloses the pipette tip (30, 40) having a second opening (at the top end thereof) capable of being adapted to removably receive a syringe (not shown) in order to draw a fluid from the distal opening of the pipette tip through the sorbent material (34 or 42) and the filter (38 or 44) and into the syringe, as in figs. 5 and 7.

22. With regards to claim 11, Mehl also discloses the sorbent material (42) comprising particles or beads (42) having diameters and wherein the distal opening (being covered by a bottom membrane 44) having a diameter of about 2 – 10 times the maximum diameter of the sorbent material/particles (42), as in fig. 7.

23. With respect to claim 35, Mehl discloses a sorbent cartridge for use in preparing samples for chemical analysis comprising a tip (30 or 40) having a longitudinal axis and a distal tip having cavity walls (32 or 40) that define an interior cavity extending along the axis with an opening at a distal end of the tip, a porous barrier (38 or top membrane 44) in the cavity placed at a predetermined location in the tip to define a sorbent volume between the barrier (38 or 44), the cavity walls (32 or 40) and the opening in the distal end of the tip (covered by another barrier or membrane 36 or bottom membrane 44), and the barrier (38 or 44) allowing processing fluids to pass therethrough and a sorbent material (34 or 42) in the sorbent volume and extending from the opening toward the barrier, the sorbent material (34 or 42) being selected for use in the chemical analysis and the barrier being selected to prevent passage of the sorbent material out of the sorbent volume, as in figs. 5 and 7 and cols. 3 – 5.

24. Concerning claim 37, Mehl further discloses the tip forming a tapered cavity ending at the distal end, as in figs. 5 and 7.

25. With respect to claim 38, Mehl also discloses the sorbent material (34 or 42) substantially filling the sorbent volume, as in figs. 5 and 7.

26. With regards to claim 43, Mehl discloses the sorbent (42) comprising a plurality of particles/beads filling between at least about 50 - 60% of the sorbent volume, as in fig. 7.

27. Concerning claim 44, Mehl further discloses the cartridge (30 or 40) further comprising one of a frit or screen, in the form of a second retainer (36) or membrane (44), at the opening and placed to prevent the sorbent material (34 or 42) from passing out of the opening, as in figs. 5 and 7.

28. Regarding claim 45, Mehl discloses the sorbent material (42) comprising particles having diameters and wherein the distal opening has a diameter of about 2 – 10 times the maximum diameter of the particles, as in fig. 7.

29. With regards to claim 46, Mehl discloses a sorbent cartridge for use in preparing samples for chemical analysis comprising a tip (30 or 40) having a longitudinal axis and a distal tip having cavity walls (32 or 40) that define an interior cavity extending along the axis with an opening at a distal end of the tip, a porous barrier (38 or top membrane 44) in the cavity placed at a predetermined location in the tip to define a sorbent volume between the barrier (38 or 44), the cavity walls (32 or 40) and the opening in the distal end of the tip (covered by another barrier or

membrane 36 or bottom membrane 44), and the porous barrier (38 or 44) allowing processing fluids to pass therethrough and a sorbent material (34 or 42) in the sorbent volume and extending from the opening toward the barrier, the sorbent material (34 or 42) being selected for use in the chemical analysis and the barrier being selected to prevent passage of the sorbent material out of the sorbent volume while allowing the passage of liquids, as in figs. 5 and 7 and cols. 3 – 5.

30. With respect to claim 47, Mehl also discloses the tip (30, 40) being tapered towards the opening in the distal end of the tip, as in figs. 5 and 7.

31. Concerning claim 48, Mehl further discloses the sorbent material (34 or 42) substantially filling all of the sorbent volume, as in figs. 5 and 7.

32. Regarding claim 49, Mehl discloses the distal tip or tip at the distal end of the pipette tip, being conical, as in fig. 5 and 7.

33. With regards to claim 50, Mehl also discloses the distal tip or tip at the distal end of the pipette tip, being tapered at least immediately adjacent the opening in the pipette tip, as in fig. 7.

34. Claims 35 – 39, 43 – 52 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Updike (US 4,138,474).

35. With regards to claim 35, Updike discloses a sorbent cartridge (10) for use in preparing samples for chemical analysis comprising a tip (10, 12) having a longitudinal axis and a distal tip having cavity walls that define an interior cavity (20) extending along the axis with an opening at a distal end (12) of the tip, a porous barrier (18) in the cavity placed at a predetermined location in the tip (10) to define a sorbent volume between the barrier (18), the cavity walls and the opening in the distal end (12) of the tip and the barrier (18) allowing processing fluids to pass therethrough and a sorbent material (22) in the sorbent volume and extending from the opening toward the barrier (18), the sorbent material (22) being selected for use in the chemical analysis and the barrier being selected to prevent passage of the sorbent material out of the sorbent volume, as in the figure and cols. 1 – 6.

36. Regarding claim 36, Updike further discloses the cavity walls at the opening extending toward the longitudinal axis to form a lip that helps retain the sorbent material (22) in the cavity (20), thereby having a tapering or narrowing cross-section, as in the figure.

37. With respect to claim 37, Updike also discloses the tip forming a tapered cavity ending at the distal end (12), as in the figure.

38. Concerning claim 38, Updike discloses the sorbent material (22) substantially filling the sorbent volume, as in the figure.

39. With regards to claim 39, Updike also discloses the sorbent material (22) comprising a plurality of particles coated with a material (antibody binding protein and gel coating) that helps the sorbent material (22) from sliding out of the opening at the distal end (12), as in cols. 1 – 6.

40. With respect to claim 43, Updike further discloses the sorbent material (22) comprising a plurality of particles (22) filling at least between about 50 – 60 % of the sorbent volume, as in the figure.

41. Regarding claim 44, Updike discloses an additional nylon net or other porous layers (frit or screen) being placed at the opening and placed to prevent the sorbent from passing out of the opening at distal end (12), as in col. 5, lines 58 – 65.

42. Concerning claim 45, Updike discloses the sorbent material (22) comprising particles (22) having diameters and the distal opening (at 12) having a diameter of at least about 2 – 10 times the maximum diameter of the particles (22), as in the figure.

43. With respect to claim 46, Updike discloses a sorbent cartridge (10) for use in preparing samples for chemical analysis comprising a tip (10, 12) having a longitudinal axis and a distal tip having cavity walls that define an interior cavity (20) extending along the axis with an opening at a distal end (12) of the tip, a porous barrier (18) at not more than one location inside

the cavity in the tip (10) and defining a sorbent volume between the barrier (18), the cavity walls and the opening in the distal end (12) of the tip and the barrier (18) allowing processing fluids to pass therethrough and a sorbent material (22) in the sorbent volume and extending from the opening toward the barrier (18), the sorbent material (22) being selected for use in the chemical analysis and the barrier being selected to prevent passage of the sorbent material out of the sorbent volume, as in the figure and cols. 1 – 6.

44. Regarding claim 47, Updike further discloses the tip (10) is tapered toward the opening in the distal end (12) of the tip, as in the figure.

45. With regards to claim 48, Updike also discloses the sorbent material substantially filling all of the sorbent volume, as in the figure.

46. Concerning claim 49, Updike discloses the distal tip (lower end of 10) is conical, as in the figure.

47. Regarding claim 50, Updike discloses the distal tip is tapered at least immediately adjacent the opening in the tip, as in the figure.

48. With respect to claim 51, Updike discloses a sorbent cartridge (10) for use in preparing samples for chemical analysis comprising a tip (10, 12) having a longitudinal axis and

a distal tip having cavity walls that define a tapered interior cavity (including 20 and up to the end 12) extending along the axis with an opening at a distal end (12) of the tip, a porous barrier (18) at not more than one location inside the cavity in the tip (10) and defining a sorbent volume between the barrier (18), the cavity walls and the opening in the distal end (12) of the tip and the barrier (18) allowing processing fluids to pass therethrough and a sorbent material (22) in the sorbent volume and extending from the opening toward the barrier (18), the sorbent material (22) being selected for use in the chemical analysis and the barrier being selected to prevent passage of the sorbent material out of the sorbent volume, as in the figure and cols. 1 – 6.

49. Concerning claim 52, Updike discloses a sorbent cartridge (10) for use in preparing samples for chemical analysis comprising a tip (10, 12), which could be a tip of a pipette device (i.e. pipette tip) having a longitudinal axis and a hollow distal tip with tapered walls defining an interior cavity (including 20 and up to the end 12) extending along the axis with an opening at a distal end (12) of the tip, a porous barrier (18) in the tapered cavity at a predetermined location in the tip to define a sorbent volume between the barrier (18), the cavity walls and the opening in the distal end (12) of the tip and the barrier (18) allowing processing fluids to pass therethrough and a sorbent material (22) in the sorbent volume and extending from the opening toward the barrier (18), the sorbent material (22) being selected for use in the chemical analysis and the barrier being selected to prevent passage of the sorbent material out of the sorbent volume, and the sorbent material comprising a plurality of particles (22) with a coating (gel and antibody

binding protein) that is sticky enough to cause the particles to stick together and resist passage out of the opening in the tip, as in the figure and cols. 1 – 6.

50. With regards to claim 54, Updike discloses a sorbent cartridge (10) for use in preparing samples for chemical analysis comprising a tip (10, 12), which could be a tip of a pipette device (i.e. pipette tip) having an interior cavity (including 20 and up to the end 12) in fluid communication with a distal opening located at a distal end (12) of/in the tip, a filter (18) placed in the tip and defining a predetermined volume between the barrier/filter (18) and the (distal) opening in the distal end (12) of the tip, and a sorbent material (22) substantially filling the volume and the filter (18) retaining the sorbent material (22) in the predetermined volume while allowing the passage of processing fluids therethrough during use of the cartridge, and the sorbent material (22) comprising a plurality of particles (22) having a coating of a solvent (gel and antibody binding protein) that is sticky enough to cause the particles to stick together and resist passage out of the opening in the tip, as in the figure and cols. 1 – 6.

Claim Rejections - 35 USC § 103

51. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

52. Claims 5 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehl (058).

53. Concerning claim 5, although Mehl does not disclose the method of making the sorbent cartridge, particularly the steps recited in claim 5 which is placing the sorbent material in the cartridge by drawing a slurry of solvent and the sorbent material through the opening in the distal end of the tip, with the slurry solvent passing through the porous barrier to leave the sorbent (material) in the sorbent volume. However, since the prior art (i.e. Mehl) product has already met the structural limitations of the claimed invention as recited in the base claim 1 (see paragraph 18 above), the examiner has considered that the prior art product (i.e. the sorbent cartridge) of Mehl is the same one, if not an obvious modification of the claimed invention. Claim 5 is considered to be a product by process claim. The patentability of a product by process claim is based upon the product itself, even though the claim is limited and defined by process, and therefore, the product in such a claim is unpatentable if it is the same as, or obvious from the product of the prior art, even if the product of the prior art had been made by a different process. See In re Thorpe, et al., No. 85-1913 (11-21-85) 227 USPQ pages 964 – 966.

54. With regards to claim 10, Mehl further discloses the predetermined volume (below the filter/barrier 38) towards the distal opening in the pipette tip (30 or 40) being tapered to form

a frusto-conical shaped cavity, as in figs. 5 and 7. Although Mehl does not disclose the shape of the filter or barrier (38 or 44) being frusto-conical, it is considered obvious to one of ordinary skill in the art to modify the shape of the filter (38 or 44) such that it has a frusto-conical shape in order to provide an alternative design for the filter (such as the one filter 18 embodiment taught by Mehl), which does not require additional means for retaining/fastening the filter or barrier (38 or 44) in the tip (30 or 40), thereby eliminating costs of using adhesives or other fastening means.

55. Claims 1 – 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over White (US 5,156,811) in view of Mehl (058).

56. With regards to claim 1, White discloses a sorbent cartridge (10) comprising a pipette tip (12) having a longitudinal axis and a hollow distal tip (at 16) with tapered walls defining an interior cavity (occupied by space 32 and liquid 34) extending along the axis and opening at a distal end (16) of the tip, a sorbent material (18) in the tapered cavity placed at a predetermined in the tip defining a sorbent volume and the sorbent material being selected for use in chemical analysis, as in figs. 1 – 2 and cols. 1 – 4. White fails to disclose a porous barrier in the tapered cavity which allows processing fluids therethrough but prevents passage of the sorbent material out of the sorbent volume. Mehl teaches a similar but improved sorbent cartridge (30, 40) to the one disclosed by White, the sorbent cartridge (30 or 40) including a pipette tip (32, 40) having a longitudinal axis and a hollow distal tip with tapered walls defining

an interior cavity extending along the axis and an opening at a distal end of the tip, a (first, at the top) porous barrier (in the form of top membrane or retainer 38, 44) in the tapered cavity placed at a predetermined location in the pipette tip (12, 32) to define a sorbent volume between the barrier (38, 44), the cavity walls of the pipette tip (12, 32) and the opening (being covered by another porous barrier 18, 36, 44) at the distal end of the pipette tip (12, 32), wherein the (first) barrier (38, top membrane 44) allowing processing fluids to pass through the barrier (38, 44), and further comprising a sorbent material (34, 42) in the sorbent volume and extending from the opening (at the vicinity of the lower porous barriers/filters 36, 44) toward the barrier (top filters or membranes 38, 44) and the sorbent material (34, 42) being selected for use in chemical analysis (i.e. absorption, filtration or separation of a particular constituent of a fluid) and the barrier (38, 44) being selected to prevent passage of the sorbent material (34, 42) out of the sorbent volume, as in figs. 2, 5 and 7 and cols. 3 – 5. It is considered obvious to one of ordinary skill in the art to modify the sorbent cartridge of White, by adding the embodiments taught by Mehl, in order to provide an alternative design for and improved sorbent cartridge which has the ability to withstand forces as high as ten thousand times gravity (if used in a centrifuge), without leakage compared to their conventional counterparts (as the one shown in Fig. 1 of Mehl or that of White), and better suited in separation applications involving colloidal suspensions, which allows liquid portion/liquids of the suspension to pass through the sorbent material (42) but provides a barrier for passage of the colloid/solid materials of the suspension (see col. 5 of Mehl).

57. Regarding claim 2, White further discloses a manually operated suction device (22) on the pipette tip (10) to exert a suction on the pipette tip (10) to draw processing fluids through the opening (at first end 14) in the tip through the sorbent material (18). As a result of the combination of the teachings of Mehl to that of White, the processing fluids which have been drawn by the suction device (22) would also pass the substituted sorbent material (34 or 42) and through the porous barrier (38 or 44) of the pipette tip of Mehl.

58. With regards to claim 3, White as modified by Mehl, further teaches the pipette tip (10, 30 or 40) having a second opening (at first end 14) opposite the opening in the distal end (16) and further comprising a setter (lower end of suction device 22) configured to mate with the second opening to place a first cavity (connected to space 21) in the setter in fluid communication with the porous barrier (placed above the sorbent material 34 or 42), the setter having a plunger (26, 28) slidably received in a second cavity (defined by the cylinder 24 or upper end of 22) and placed in fluid communication with the first cavity and the plunger (26) and the second cavity sized relative to each other so as to create a suction sufficient to draw fluid from the opening (at 16) in the tip into the cavity in the setter when the plunger slides in the second cavity, as in figs. 2 and 5 – 6 and cols. 3 – 5 of White.

59. Concerning claim 4, Mehl further teaches the size of the opening (covered by bottom membrane 44) in the tip of the pipette tip (40) being from at least about 2 – 10 times the size of the material in the sorbent material (42), as in fig. 7. The same motivation applied in the

rejection of claim 1 (paragraph 56), is applied here. Furthermore, the size of the opening in the tip of the pipette tip should be at least about 2 times of the size of the material in the sorbent material, in order to allow a greater amount of processing fluid to be treated by the sorbent material at one suction/use of the suction-pipetting device.

60. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mehl in view of White (811).

61. With regards to claim 12, Mehl fails to disclose a syringe being received in the second opening of the pipette tip and containing a fluid drawn from the distal opening through the sorbent material and the filter. White teaches a device having a pipette tip/sorbent cartridge (10) to that of Mehl, further comprising a syringe (22, 44) being received in a second opening of the pipette tip (10) and containing a fluid drawn from the distal opening of the pipette tip. It is considered obvious the combination of the teachings of White to that of Mehl, would result in the fluid that was drawn from the distal tip of the pipette (of Mehl) which is connected to the syringe (22, 44) of White would result in having the fluid be drawn through the sorbent material (34 or 42) and through the filter or barrier (38 or 44) as well. It is considered obvious to one of ordinary skill in the art at the time of the invention to modify the sorbent cartridge of Mehl, by adding the embodiment taught by White, in order to provide a means for fluid flow/drawing fluid and be processed or filtered by the sorbent material and the filter, in order to remove a desired

component in the fluid being processed or filtered. The syringe is a known suction device used with a pipette tip for suction of fluids therethrough.

62. Claims 33 – 34 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Updike (US 4,138,474).

63. With respect to claim 33, Updike discloses a sorbent cartridge for use in preparing samples for chemical analysis comprising a hollow tip (10) having an opening in a distal end (near 12), a means (not shown) in the tip for retaining a porous barrier (18) at a predetermined location to define a sorbent volume between the barrier (18) and the opening in the hollow tip (10) and with no (additional or second) porous barrier being interposed between the opening and the means for retaining the porous barrier, and a sorbent material (22, 20) between the opening and the means, being retained in the sorbent volume by the porous barrier (18) for use in the chemical analysis (immunoassay) and the barrier (18) allowing passage of fluids but not the sorbent material (22) during use of the sorbent cartridge, as in the figure and cols. 2 – 3.

Although the means for retaining the porous barrier (18) of Updike is not shown, it is considered obvious, if not inherent, in the disclosure that the porous barrier (18) has some means for staying or being retained in the particular location despite having a suction force being applied against it with a suction device (10, 16, 14), as in cols. 2 – 3. This means could be an adhesive or any form of retaining or fastening means for attaching the porous barrier (18) to the inner walls of the hollow tip (10), as in the figure.

64. Concerning claim 34, Updike further discloses the sorbent cartridge further comprising a suction means (16, 14) in fluid communication with the hollow tip to suck fluid through the opening in the distal end (12) and through the sorbent material (22) and the porous barrier (18).

65. Claims 6 – 7, 13 – 14 and 40 – 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehl in view of Bozzacco et al. (US 2,806,509).

66. With respect to claims 6 and 13, Mehl also discloses the sorbent material comprising a plurality of particles (42) but fails to disclose the particles with a coating of a solvent on the particles that is sticky enough to cause the particles to stick together and resist passage out of the opening in the tip. Bozzacco et al. teach a similar sorbent material comprising a plurality of particles (hollow beads of silica gel or other types of beads, 10) with a coating of a (thermosetting resin, 12) solvent on the particles thereby making them sticky enough to cause the particles (10) to stick together, as in cols. 1 – 5 and fig. 2. It is known in the art that silica gel is a generally well-known adsorbent/sorbent material (See Webster Dictionary, page 1092 for definition of silica gel). It is considered obvious to one of ordinary skill in the art at the time of the invention to modify the sorbent material of Mehl, by substituting it with the sorbent material taught by Bozzacco et al., in order to provide an alternative form as well as an effective sorbent material which has the ability to retain itself (i.e. self-supporting) in the hollow cavity of the

pipette tip of Mehl, thereby eliminating the need of additional porous support materials such as the thin membrane (44 in Mehl) and saving costs in the manufacture of the sorbent cartridge.

67. Regarding claims 7, 14, 40 – 42, 53 and 55, Bozzacco et al. further teach the thermosetting resin (12) being used to coat the hollow beads (10) being any known customary (polyester) resin solvents including those formed of glycols and glycerols, such as ethylene glycol, propylene glycol and glycerol, as in cols. 2 – 3. It is considered obvious to one of ordinary skill in the art to use one of claimed solvents in the above mentioned claims as the binding/coating resin material for coating the particles of the sorbent material together, as matter of choice by the user and what is available to the user at the time, and in order to provide a solvent coating which is tacky for making the particles stick to each other, at the same time provide a material for the coating which is cost-efficient, thereby making the manufacturing of the sorbent material also cost-efficient. (see Hawley's Dictionary, page 34 for desirable properties of alkyd resins which include those of glycols and glycerols mentioned here).

Response to Arguments

68. Applicant's arguments with respect to claims 1 – 14 and 33 - 55 have been considered but are moot in view of the new grounds of rejection set forth in this Office action.

This action is non-final.

Conclusion

69. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,165,519 (Lehrer et al.), 5,332,426 (Tang et al.) and 6,200,474 B1 and 6,048,457 (both to Kopaciewicz et al.), and GB 2,158,057 (Degen et al.).

70. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne S. Ocampo whose telephone number is (703) 305-1039. The examiner can normally be reached on Mondays to Fridays from 8:00 A.M. to 4:30 P.M..

71. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker can be reached on (703) 308-0457. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

72. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Art Unit: 1723

M.S.O.

September 20, 2002

M. Savage
MATTHEW O. SAVAGE
PRIMARY EXAMINER